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**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

ASTRAZENECA AB, ASTRAZENECA LP,	)	
KBI-E INC., and POZEN INC.,	)	CIVIL ACTION NO. 11-cv-04275-JAP-DEA
	)	
Plaintiffs/Counter-Defendants,	)	
	)	
v.	)	<b>ASTRAZENECA AB’S, ASTRAZENECA</b>
	)	<b>LP’S, KBI-E INC.’S, AND POZEN INC.’S</b>
	)	<b>ANSWER TO LUPIN LTD.’S AND</b>
LUPIN LTD. and LUPIN	)	<b>LUPIN PHARMACEUTICALS INC.’S</b>
PHARMACEUTICALS INC.,	)	<b>COUNTERCLAIMS</b>
	)	
Defendants/Counter-Plaintiffs.	)	
	)	

Plaintiffs/Counterclaim-Defendants AstraZeneca AB, AstraZeneca LP, KBI-E, Inc., and Pozen Inc. (collectively, “Plaintiffs”), by their attorneys, for their Answer to the Counterclaims of Defendants/Counterclaim-Plaintiffs Lupin Ltd. and Lupin Pharmaceuticals Inc. (collectively, “Lupin” or “Defendants”), respond as set forth below.

**ANSWER TO DEFENDANTS’ COUNTERCLAIMS**

106. No response is required. To the extent a response is required, Plaintiffs admit that Lupin purports to allege counterclaims against Plaintiffs for a declaratory judgment that U.S. Patent Nos. 5,714,504 (“the ’504 patent”), 6,369,085 (“the ’085 patent”), 6,875,872 (“the ’872

patent”), 7,411,070 (“the ’070 patent”), 7,745,466 (“the ’466 patent”), 6,926,907 (“the ’907 patent”), and 5,900,424 (“the ’424 patent”) are invalid and/or not infringed by the products that are the subject of ANDA No. 202654, but deny there is any factual or legal basis for the allegations.

### **THE PARTIES**

107. On information and belief, Plaintiffs admit the allegations of paragraph 107.

108. On information and belief, Plaintiffs admit the allegations of paragraph 108.

109. Plaintiffs admit the allegations of paragraph 109.

110. Plaintiffs admit the allegations of paragraph 110.

111. Plaintiffs admit the allegations of paragraph 111.

112. Plaintiffs admit the allegations of paragraph 112.

### **BACKGROUND**

113. Upon information and belief, Plaintiffs admit the allegation in first sentence of paragraph 113. Plaintiffs are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in the second sentence of paragraph 113, and therefore deny the allegations.

114. Plaintiffs admit the allegation in the first sentence of paragraph 114. The second sentence of paragraph 114 contains legal conclusions to which no response is required. To the extent a response is required, Plaintiffs deny the remaining allegations of paragraph 114.

115. Plaintiffs admit that by their ANDA notice letter, Lupin notified Plaintiffs that they had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (paragraph IV) with respect to the ’504 patent, ’085 patent, ’872 patent, ’070 patent, ’466 patent, ’907 patent, and the ’424 patent, but deny that there is any factual or legal basis for

the allegations. Plaintiffs deny the remaining allegations of paragraph 115.

116. The allegations of paragraph 116 contain legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit that Plaintiffs received notice from Lupin that ANDA No. 202654 contained a paragraph IV certification on the '504 patent, '085 patent, '872 patent, '070 patent, '466 patent, '907 patent, and '424 patent, and Plaintiffs deny the remaining allegations of paragraph 116.

### **JURISDICTION AND VENUE**

117. Plaintiffs repeat and reassert all responses to paragraphs 106-116 as if they were incorporated herein.

118. Plaintiffs admit that they have brought an action against Lupin for infringement of the '504 patent, '085 patent, '872 patent, '070 patent, '466 patent, and '907 patent. The remaining allegations of paragraph 118 contain legal conclusions to which no response is required. To the extent a response is required, Plaintiffs do not contest there is a case or controversy between Plaintiffs and Lupin as to Lupin's infringement of the '504 patent, '085 patent, '872 patent, '070 patent, '466 patent, and '907 patent and deny the remaining allegations of paragraph 118.

119. The allegations of paragraph 119 contain legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit that the '424 patent is listed in the Orange Book for VIMOVO® and deny the remaining allegations of paragraph 119.

120. The allegations of paragraph 120 contain legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit that Lupin purports to state a cause of action under the Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202, 1338, 1367, and 1331, but deny that there is any factual or legal basis for the declaratory judgment

action or that Lupin is entitled to the relief it seeks. Plaintiffs do not contest that this Court has subject matter jurisdiction, for this action only, over the asserted claims of the '504 patent, '085 patent, '872 patent, '070 patent, '466 patent, and '907 patent. Plaintiffs deny the remaining allegations of paragraph 120.

121. Plaintiffs admit the allegations of paragraph 121.

**LUPIN'S PURPORTED ENTITLEMENT TO DECLARATORY JUDGMENT**

122. Plaintiffs admit that they filed an action on July 25, 2011 against Lupin alleging patent infringement under 35 U.S.C. § 271(e)(2) based on Lupin's filing of ANDA No. 202654, which seeks approval to market generic versions of Plaintiffs' VIMOVO<sup>®</sup> pharmaceutical products. Plaintiffs admit that they alleged infringement of the '504 patent, '085 patent, '872 patent, '070 patent, '466 patent, and '907 patent. Plaintiffs admit the '424 patent is listed in the Orange Book for VIMOVO<sup>®</sup>. Plaintiffs admit they have not brought an action against Lupin for infringement of the '424 patent. The remaining allegations of paragraph 122 contain legal conclusions to which no response is required. To the extent a response is required, Plaintiffs deny the remaining allegations of paragraph 122.

123. Plaintiffs admit that 21 U.S.C. § 355(j)(5)(C)(i)(I)(aa)-(cc) states: "No action may be brought under section 2201 of title 28, United States Code, by an applicant under paragraph (2) for a declaratory judgment with respect to a patent which is the subject of the certification referred to in subparagraph (B)(iii) unless— (aa) the forty-five day period referred to in such subparagraph has expired; (bb) neither the owner of such patent nor the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brought a civil action against the applicant for infringement of the patent before the expiration of such period; and (cc) in any case in which the notice provided

under paragraph (2)(B) relates to non-infringement, the notice was accompanied by a document described in subclause (III). To the extent any further response is required, Plaintiffs deny the remaining allegations in paragraph 123.

124. The allegations of paragraph 124 contain legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit that Lupin purportedly provided an offer to confidential access to its ANDA, Plaintiffs admit they have not sued Lupin on the '424 patent, Plaintiffs admit that 45 days have passed since they received Lupin's paragraph IV certification, and Plaintiffs deny the remaining allegations of paragraph 124.

125. The allegations of paragraph 125 contain legal conclusions to which no response is required. To the extent a response is required, Plaintiffs deny the allegations of paragraph 125.

**ANSWER TO FIRST COUNTERCLAIM**  
**Declaration of Non-Infringement of the '504 Patent**

126. Plaintiffs repeat and reassert all responses to paragraphs 106-125 as if they were incorporated herein.

127. Plaintiffs deny the allegations of paragraph 127.

128. The allegations of paragraph 128 contain legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit the allegations in paragraph 128.

**ANSWER TO SECOND COUNTERCLAIM**  
**Declaration of Invalidity of the '504 Patent**

129. Plaintiffs repeat and reassert all responses to paragraphs 106-125 as if they were incorporated herein.

130. Plaintiffs deny the allegations of paragraph 130.

131. The allegations of paragraph 131 contain legal conclusions to which no response

is required. To the extent a response is required, Plaintiffs admit the allegations in paragraph 131.

**ANSWER TO THIRD COUNTERCLAIM**  
**Declaration of Non-Infringement of the '085 Patent**

132. Plaintiffs repeat and reassert all responses to paragraphs 106-125 as if they were incorporated herein.

133. Plaintiffs deny the allegations of paragraph 133.

134. The allegations of paragraph 134 contain legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit the allegations in paragraph 134.

**ANSWER TO FOURTH COUNTERCLAIM**  
**Declaration of Invalidity of the '085 Patent**

135. Plaintiffs repeat and reassert all responses to paragraphs 106-125 as if they were incorporated herein.

136. Plaintiffs deny the allegations of paragraph 136.

137. The allegations of paragraph 137 contain legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit the allegations in paragraph 137.

**ANSWER TO FIFTH COUNTERCLAIM**  
**Declaration of Non-Infringement of the '872 Patent**

138. Plaintiffs repeat and reassert all responses to paragraphs 106-125 as if they were incorporated herein.

139. Plaintiffs deny the allegations of paragraph 139.

140. The allegations of paragraph 140 contain legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit the allegations in paragraph 140.

**ANSWER TO SIXTH COUNTERCLAIM**  
**Declaration of Invalidity of the '872 Patent**

141. Plaintiffs repeat and reassert all responses to paragraphs 106-125 as if they were incorporated herein.

142. Plaintiffs deny the allegations of paragraph 142.

143. The allegations of paragraph 143 contain legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit the allegations in paragraph 143.

**ANSWER TO SEVENTH COUNTERCLAIM**  
**Declaration of Non-Infringement of the '070 Patent**

144. Plaintiffs repeat and reassert all responses to paragraphs 106-125 as if they were incorporated herein.

145. Plaintiffs deny the allegations of paragraph 145.

146. The allegations of paragraph 146 contain legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit the allegations in paragraph 146.

**ANSWER TO EIGHTH COUNTERCLAIM**  
**Declaration of Invalidity of the '070 Patent**

147. Plaintiffs repeat and reassert all responses to paragraphs 106-125 as if they were incorporated herein.

148. Plaintiffs deny the allegations of paragraph 148.

149. The allegations of paragraph 149 contain legal conclusions to which no response

is required. To the extent a response is required, Plaintiffs admit the allegations in paragraph 149.

**ANSWER TO NINTH COUNTERCLAIM**  
**Declaration of Non-Infringement of the '466 Patent**

150. Plaintiffs repeat and reassert all responses to paragraphs 106-125 as if they were incorporated herein.

151. Plaintiffs deny the allegations of paragraph 151.

152. The allegations of paragraph 152 contain legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit the allegations in paragraph 152.

**ANSWER TO TENTH COUNTERCLAIM**  
**Declaration of Invalidity of the '466 Patent**

153. Plaintiffs repeat and reassert all responses to paragraphs 106-125 as if they were incorporated herein.

154. Plaintiffs deny the allegations of paragraph 154.

155. The allegations of paragraph 155 contain legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit the allegations in paragraph 155.

**ANSWER TO ELEVENTH COUNTERCLAIM**  
**Declaration of Non-Infringement of the '907 Patent**

156. Plaintiffs repeat and reassert all responses to paragraphs 106-125 as if they were incorporated herein.

157. Plaintiffs deny the allegations of paragraph 157.

158. The allegations of paragraph 158 contain legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit the allegations in paragraph 158.



**ANSWER TO TWELFTH COUNTERCLAIM**  
**Declaration of Invalidity of the '907 Patent**

159. Plaintiffs repeat and reassert all responses to paragraphs 106-125 as if they were incorporated herein.

160. Plaintiffs deny the allegations of paragraph 160.

161. The allegations of paragraph 161 contain legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit the allegations in paragraph 161.

**ANSWER TO THIRTEENTH COUNTERCLAIM**  
**Declaration of Non-Infringement of the '424 Patent**

162. Plaintiffs repeat and reassert all responses to paragraphs 106-125 as if they were incorporated herein.

163. Plaintiffs deny the allegations of paragraph 163.

164. The allegations of paragraph 164 contain legal conclusions to which no response is required. To the extent a response is required, Plaintiffs deny the allegations in paragraph 164.

**ANSWER TO FOURTEENTH COUNTERCLAIM**  
**Declaration of Invalidity of the '424 Patent**

165. Plaintiffs repeat and reassert all responses to paragraphs 106-125 as if they were incorporated herein.

166. Plaintiffs deny the allegations of paragraph 166.

167. The allegations of paragraph 167 contain legal conclusions to which no response is required. To the extent a response is required, Plaintiffs deny the allegations in paragraph 167.

Plaintiffs further deny each allegation contained in Lupin's Counterclaim that was not specifically admitted, denied, or otherwise responded to in its Answer to Defendants' counterclaims.

**RESPONSE TO LUPIN'S PRAYER FOR RELIEF**

Plaintiffs deny that Lupin is entitled to any relief as sought in its Counterclaims.

WHEREFORE, Plaintiffs therefore respectfully request the following relief:

- A. Dismissing Lupin's Counterclaims with prejudice and denying all relief sought by Lupin;
- B. Awarding Plaintiffs the relief requested in their Complaint; and
- C. Awarding Plaintiffs any further and other relief as this Court deems just and proper.

Dated: October 20, 2011

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**CERTIFICATE OF SERVICE**

I hereby certify that on October 20, 2011, I caused the foregoing Plaintiffs' Answer to Lupin Ltd.'s and Lupin Pharmaceuticals Inc.'s Counterclaims to be served upon the following counsel via electronic mail and the CM/ECF system:

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